**EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

2. Authorization for this examiner's amendment was given in a telephone interview with Gary J. Connell on July 16, 2010.

3. The application has been amended as follows:

In the claims:

1-60. (Cancelled)

61-65. (Not entered)

66-70. (Cancelled)

71. (Currently Amended) A method of identifying the presence of human mammary carcinoma ~~detecting amplification of a gene~~ in mammary tissue from a human, said method comprising ~~detecting~~ determining whether ~~amplification of~~ a gene that encodes a protein comprising amino acid sequence SEQ ID NO:1 ~~occurs~~ is amplified in said tissue when the level of the occurrence of the gene in the said tissue is greater than the level of occurrence of the gene in normal mammary tissue, wherein amplification of the gene in said mammary tissue from said human relative to normal human mammary tissue is indicative of the presence of human mammary carcinoma in said mammary tissue from said human.

72. (Previously Presented) The method of Claim 71, wherein said gene comprises nucleic acid sequence SEQ ID NO:2.

73. (Previously Presented) The method of Claim 71, wherein said gene encodes a protein comprising the protein encoded by the Bam HI DNA fragment contained in the pUC12 subclone in the E. coli strain deposited under ATCC accession number 53408.

74. (Previously Presented) The method of Claim 71, wherein said gene comprises the nucleic acid sequence of the Bam HI DNA fragment contained in the pUC12 subclone in the E. coli strain deposited under ATCC accession number 53408.

75. (Currently Amended) A method of identifying the presence of human mammary carcinoma ~~detecting amplification of a gene~~ in mammary tissue from a human, said method comprising analyzing for amplification of DNA of a gene that encodes a protein comprising amino acid sequence SEQ ID NO:1, wherein amplification is present in said tissue when the amount of the DNA of the gene in said tissue is greater than the amount of the DNA of the gene in normal mammary tissue and wherein amplification of the DNA of the gene in said mammary tissue from said human ~~relative to normal human mammary tissue~~ is indicative of the presence of human mammary carcinoma in said mammary tissue from said human.

76. (Previously Presented) The method of Claim 75, wherein said gene comprises nucleic acid sequence SEQ ID NO:2.

77. (Previously Presented) The method of Claim 75, wherein said gene encodes a protein comprising the protein encoded by the Bam HI DNA fragment contained in the pUC12 subclone in the E. coli strain deposited under ATCC accession number 53408.

78. (Previously Presented) The method of Claim 75, wherein said gene comprises the nucleic acid sequence of the Bam HI DNA fragment contained in the pUC12 subclone in the E. coli strain deposited under ATCC accession number 53408.

79-87. (Canceled)

88. (Currently Amended) The method of Claim 75, wherein the step of analyzing comprises ~~hybridizing~~ contacting DNA of the human mammary tissue with a nucleic acid probe [[from]] that hybridizes to the DNA of [[a]] the gene that encodes a protein comprising amino acid sequence SEQ ID NO: 1, measuring the amount of the probe that hybridizes to the DNA of the human mammary tissue, and determining that the DNA of the gene is amplified in the mammary tissue from the human when the amount of probe hybridizing to the DNA of the mammary tissue is greater than the amount of probe hybridizing to DNA in normal mammary tissue.

89. (Currently Amended) The method of Claim 75, wherein the step of analyzing comprises isolating DNA from the human mammary tissue and ~~hybridizing~~ contacting the DNA with a nucleic acid probe [[from]] that hybridizes to the DNA of [[a]] the gene that encodes a protein comprising amino acid sequence SEQ ID NO:1, measuring the amount of the probe that hybridizes to the DNA from the human mammary tissue, and determining that the DNA from the gene is amplified in the mammary tissue from the human when the amount of probe hybridizing to the DNA in the mammary tissue is greater than the amount of probe hybridizing to DNA in normal mammary tissue.

90. (Canceled)

91. (Canceled)

92. (New) The method of Claim 75, wherein analyzing for amplification of DNA of a gene that encodes a protein comprising amino acid sequence SEQ ID NO:1 is performed by Southern blot analysis.

93. (New) The method of Claim 75, further comprising determining whether the gene is overexpressed in the mammary tissue from the human, wherein the overexpression of the gene provides further indication of the presence of human mammary carcinoma in the mammary tissue from the human.

94. (New) The method of Claim 93, wherein determining whether the gene is overexpressed in the mammary tissue from the human comprises measuring the level of mRNA encoding a protein comprising amino acid sequence SEQ ID NO:1 in mammary tissue from the human and comparing the measured level to the level of the mRNA occurring in normal mammary tissue.

95. (New) The method of Claim 93, wherein determining whether the gene is overexpressed in the mammary tissue from the human comprises measuring the level of a protein comprising amino acid sequence SEQ ID NO:1 in the mammary tissue from the human and comparing the measured level to the level of the protein occurring in normal mammary tissue.

96. (New) The method of Claim 95, wherein the level of the protein is measured by reacting an antibody prepared against said protein with said human mammary tissue.

***Conclusion***

4. Claims 71-78, 88, 89, and 92-96 have been allowed.

5. Claims 71-78, 88, 89, and 92-96 have been renumbered as claims 1-15, respectively.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Montgomery et al. (*Proc. Natl. Acad Sci. U S A.* 1983 Sep; **80** (18): 5724-5728) teaches an analysis of gene amplification in neuroblastoma. Brison et al. (*Biochim. Biophys. Acta.* 1993 May 25; **1155** (1): 25-41) reviews gene amplification in tumors. Kozbor et al. (*Cancer Res.* 1984 Feb; **44** (2): 438-441) teaches amplification of the c-myc oncogene in breast cancer. Filmus et al. (*Biochem. Biophys. Res. Commun.* 1985 Apr 30; **128** (2): 898-905) teaches amplification of the gene encoding EGF receptor in breast cancer. Yander et al. (*Cancer Res.* Sep; **45** (9): 4433-4438) teaches amplification of c-myc in colon tumors. Kohl et al. (*Cell.* 1983 Dec; **35** (Pt 1): 359-367) teaches amplification of oncogenes in neuroblastomas.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephen L. Rawlings/
Primary Examiner, Art Unit 1643

slr
July 17, 2010